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TC

## NOTICE OF ALLOWANCE AND FEE(S) DUE

000513 7590 02/19/2004

WENDEROTH, LIND & PONACK, L.L.P.  
2033 K STREET N. W.  
SUITE 800  
WASHINGTON, DC 20006-1021

EXAMINER

SPEAR, JAMES M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 02/19/2004

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,835	12/17/2001	Kazuhiro Ohkouchi	2001-1692A	3505

TITLE OF INVENTION: QUICKLY DISINTEGRATING SOLID PREPARATIONS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1330	\$0	\$1330	05/19/2004

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. **PROSECUTION ON THE MERITS IS CLOSED.** THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

### HOW TO REPLY TO THIS NOTICE:

#### I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

☐ Applicant claims SMALL ENTITY status.  
See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER:** Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

# **PART B - FEE(S) TRANSMITTAL**

**Complete and send this form, together with applicable fee(s), to: Mail**

**Mail Stop ISSUE FEE  
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P.O. Box 1450  
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or Fax (703) 746-4000**

**INSTRUCTIONS:** This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

000513 7590 02/19/2004

**WENDEROTH, LIND & PONACK, L.L.P.  
2033 K STREET N. W.  
SUITE 800  
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Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

## **Certificate of Mailing or Transmission**

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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nonprovisional	NO	\$1330	\$0	\$1330	05/19/2004

EXAMINER	ART UNIT	CLASS-SUBCLASS
SPEAR, JAMES M	1615	424-480000

**1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).**

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

**2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.**

1	_____
2	_____
3	_____

**3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)**

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent); ☐ individual ☐ corporation or other private group entity ☐ government

**4a. The following fee(s) are enclosed:**

- ☐ Issue Fee
- ☐ Publication Fee
- ☐ Advance Order - # of Copies \_\_\_\_\_

**4b. Payment of Fee(s):**

- ☐ A check in the amount of the fee(s) is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

Director for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

(Authorized Signature)

(Date)

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Alexandria, Virginia 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Alexandria, Virginia 22313-1450.**

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TRANSMIT THIS FORM WITH FEE(S)



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WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021				
			EXAMINER SPEAR, JAMES M	
			ART UNIT 1615	PAPER NUMBER

DATE MAILED: 02/19/2004

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (703) 305-1383. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

**Notice of Allowability**

Application No.

10/009,835

Examiner

James M Spear

Applicant(s)

OHKOUCHI ET AL.

Art Unit

1615

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to The amendment filed January 21, 2004.
2. ☒ The allowed claim(s) is/are 19-32.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

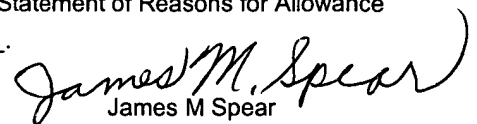
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

  
James M Spear  
Primary Examiner  
Art Unit: 1615

Art Unit: 1615

1. The following is an examiner's statement of reasons for allowance:
  - a. Applicants show s quickly disintegrating solid preparation comprised of an active ingredient, a saccharide or sugar alcohol, a disintegrating agent and a cellulose compound. Quick disintegrating tablets are known. The ingredients are disclosed in prior art references EP 0 839 526 A2 and WO 98/53798, considered the closest prior art of record. The prior art does not show nor fairly suggest the particular combination of a fine powder and coarse powder in a quickly disintegrating tablet comprised of the above-mentioned ingredients. In particular a saccharide or sugar alcohol with a mean particle diameter of 5 microns to below 90 microns and a saccharide or sugar alcohol with a mean particle diameter of 90 microns to 500 microns is formulated with an active ingredient, a disintegrating agent and a cellulose compound to provide a tablet having the requisite properties for applicants' quickly disintegrating solid preparation.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Claims 19-32 are allowed.

Claims 1-18 have been canceled.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M Spear whose telephone number is 571 272

Art Unit: 1615

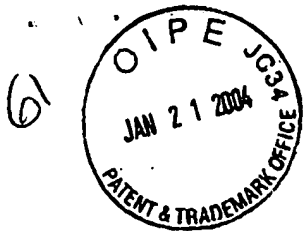
0605. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page, can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
James M Spear  
Primary Examiner  
Art Unit 1615

February 10, 2004



Corres. and Mail  
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JAN 23 2004  
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of : **Confirmation No. 3505**  
Kazuhiro OHKOUCHI et al. : **Docket No. 2001\_1692A**  
Serial No. 10/009,835 : **Group Art Unit 1615**  
Filed December 17, 2001 : **Examiner James M. Spear**

QUICKLY DISINTEGRATING SOLID PREPARATIONS

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1615

**AMENDMENT AFTER FINAL**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Responsive to the Official Action dated November 19, 2003, please amend the above-identified application as follows:

### Amendments to the Claims

1-18. (Cancelled)

<sup>1</sup>  
~~19.~~ (Currently amended) A quickly disintegrating solid preparation comprising a) an active ingredient, b-1) a saccharide or sugar alcohol with ~~the~~ a mean particle diameter of 5  $\mu$ m to below 90  $\mu$ m, b-2) a saccharide or sugar alcohol with a ~~the~~ mean particle diameter of 90  $\mu$ m to 500  $\mu$ m, c) a disintegrating agent, and d) a cellulose compound.

<sup>1</sup>  
<sup>2</sup>  
~~20.~~ (Original) The preparation according to claim ~~19~~, which contains 0.1 to 10 parts of the ingredient b-2) per 1 part of the ingredient b-1) by weight.

<sup>1</sup>  
<sup>3</sup>  
~~21.~~ (Currently amended) The preparation according to claim ~~19~~, ~~characterized in that wherein~~ a mixture of the ingredient b-1) and the ingredient b-2) is used as the ingredient b-1) and the ingredient b-2).

<sup>3</sup>  
<sup>4</sup>  
~~22.~~ (Original) The preparation according to claim ~~21~~, wherein the mean particle diameter of the mixture is 30  $\mu$ m to 300  $\mu$ m.

<sup>1</sup>  
<sup>5</sup>  
~~23.~~ (Original) The preparation according to claim ~~19~~, wherein the mean particle diameter of the ingredient b-1) is 30  $\mu$ m to below 90  $\mu$ m.

<sup>1</sup>  
<sup>6</sup>  
~~24.~~ (Original) The preparation according to claim ~~19~~, wherein the mean particle diameter of the ingredient b-1) is 35  $\mu$ m to 80  $\mu$ m.

<sup>1</sup>  
<sup>7</sup>  
~~25.~~ (Original) The preparation according to claim ~~19~~, wherein the mean particle diameter of the ingredient b-2) is 90  $\mu$ m to 300  $\mu$ m.



8  
26. (Original) The preparation according to claim 19, wherein the mean particle diameter of the ingredient b-2) is 90  $\mu$ m to 200  $\mu$ m.

9  
27. (Original) The preparation according to claim 19, wherein the saccharide is one or more saccharides selected from the group consisting of glucose, fructose, lactose, sucrose, and trehalose.

10  
28. (Original) The preparation according to claim 19, wherein the sugar is lactose.

11  
29. (Original) The preparation according to claim 19, wherein the sugar alcohol is one or more sugar alcohols selected from the group consisting of D-mannitol, erythritol, xylitol, maltitol, and sorbitol.

12  
30. (Original) The preparation according to claim 19, wherein the sugar alcohol is D-mannitol.

13  
31. (Currently amended) The preparation according to claim 19, characterized in that wherein D-mannitol with ~~the~~ a mean particle diameter of 30  $\mu$ m to below 90  $\mu$ m and D-mannitol with ~~the~~ a mean particle diameter of 90  $\mu$ m to 300  $\mu$ m are used as the ingredient b-1) and the ingredient b-2), respectively.

14  
32. (Currently amended) ~~The procedure~~ A method for production of the preparation according to claim 19, ~~characterized in that~~ which comprises compression molding a mixture containing a) an active ingredient, b-1) a saccharide or sugar alcohol with ~~the~~ a mean particle diameter of 5  $\mu$ m to below 90  $\mu$ m, b-2) a saccharide or sugar alcohol with ~~the~~ a mean particle diameter of 90  $\mu$ m to 500  $\mu$ m, c) a disintegrating agent, and d) a cellulose compound, ~~is subjected to compression molding.~~

### REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Claims 1-18 are cancelled without prejudice.

The rejection of claims 1-18 under 35 USC 102 as anticipated by WO 98/53798, and the rejection of claims 1-13 and 18 under 35 USC 102 as anticipated by EP 0 839 526, is thus deemed to be overcome.

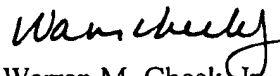
Applicants acknowledge with thanks the Examiner's indication that claims 19-32 are allowed. Claims 19-32 have been amended to make editorial changes consistent with U.S. practice.

Favorable action and allowance is solicited.

Respectfully submitted,

Kazuhiro OHKOUCHI et al.

By:



Warren M. Cheek, Jr.

Registration No. 33,367

Attorney for Applicants

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January 21, 2004